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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products  
 Liability Litigation

No. MD-15-02641-PHX-DGC

SHERR-UNA BOOKER, an individual,

**PLAINTIFF'S EXPLANATION OF SNF  
 DOCUMENTS**

Plaintiff,

(The Honorable David G. Campbell)

v.

C.R. BARD, INC., a New Jersey  
 corporation and BARD PERIPHERAL  
 VASCULAR, an Arizona corporation,

Defendants.

Plaintiff respectfully submits an explanation of the submitted SNF documents regarding Objections to Bard's Simon Nitinol Filter evidence [Minute Order; Doc 10485]. By way of background, early in this MDL, Plaintiffs argued that SNF design and testing documents as well as adverse events and complaint files were relevant to assess Bard's claim that later filters were substantially equivalent to the SNF. Bard vigorously opposed production of those materials over Plaintiffs' contention that SNF "design, testing, ... adverse events, [etc.] . . . are all relevant to the efficacy of the later devices based on its design." [Joint Report for CMO #2.] Plaintiff clarified at the January 29, 2016 Case Management Conference that, for example, the fatigue bench testing for SNF and related

1 acceptance criteria were relevant to compare with the fatigue testing of the Recovery and  
 2 G2 filters. [Transcript, p. 136:2-13, 137:8-138:2.] The Court ruled that “[it] does not  
 3 believe that discovery related to the design or testing of the SNF is relevant to this case.  
 4 Plaintiffs do not contend that the SNF is defective.” [CMO 10, Doc. 1319.]

5 Discovery into the design and testing of the SNF would have permitted Plaintiff to  
 6 challenge Bard’s litigation-created assertion that the SNF had as many failures as the  
 7 Recovery and G2 filters. Further, the hearsay documents Bard proposes to rely on relate to  
 8 earlier versions of the SNF, which received safety-related design changes up through at  
 9 least 1995; so studies relying information gathered on pre-1995 SNF filters, in particular,  
 10 should be excluded. The submitted documents are illustrative of the SNF information  
 11 produced by Bard and serve to highlight the information that is not available to Plaintiff.  
 12 Plaintiff respectfully directs the Court’s attention to the following in the submitted  
 13 documents, identified by number:

- 14 • #283: Page 3 provides an example of the SNF data produced in discovery—that Bard  
 15 had zero reports of SNF fatalities and tils, and 2 reports of migrations and fractures  
 with over 75,000 units sold.
- 16 • #530: Page 1 shows that the 510(k) application for FDA clearance for the Recovery  
 17 filter identified the SNF filter as a predicate devices. Page 3 indicates that the FDA  
 cleared the Recovery filter as substantially equivalent to the SNF filter.
- 18 • #709: Page 6 provides an example of the SNF performance that Bard now tries to  
 19 contradict: “Throughout its over two decades of clinical use, no evidence has been  
 found to support a link between SNF permanent filter implantation and the serious  
 health consequences that have been an expressed concern from FDA regarding  
 removable IVC filters.”
- 20 • #992: Similar to #709, page 2 contains the statement “may I suggest the safest filter  
 on the market . . . for the longest time in its current form... The Simon Nitinol?”
- 21 • #999: Similarly, Page 1 contains the question “The G2 is a permanent filter; we also  
 have one (the SNF) that has virtually no complaints associated with it.”
- 22 • #1343: Similarly, on page 2 (top): “We have . . . experienc[ed] a very low and  
 unremarkable adverse event rate [with SNF].”
- 23 • #1548: Generally, a 1997 technical file for the SNF. Pages 28-30 provide examples  
 of the testing performed, for which Bard did not produce details.
- 24 • #1729: Page 1 provides another example of Bard’s low complaint rate with SNF for  
 fatalities and migrations.

25 In summary, Plaintiff will be unable to contradict the hearsay documents Bard intends  
 26 to rely on because the relevance and correct interpretation of the results from those articles  
 27 depends on the precise version of the SNF filter at issue and the testing criteria used with  
 28 each version of the SNF.

1 RESPECTFULLY SUBMITTED this 29<sup>th</sup> day of March, 2018.

2 GALLAGHER & KENNEDY, P.A.

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13 **CERTIFICATE OF SERVICE**

14 I hereby certify that on this 19<sup>th</sup> day of March, 2018, I electronically transmitted the  
15 attached document to the Clerk's Office using the CM/ECF System for filing and transmittal  
16 of a Notice of Electronic Filing.

17 /s/ Gay Mennuti  
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